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ISSUE 7 | FEBRUARY 10, 2011

BIOTECH LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

Judiciary Committee Sends Patent Reform Bill to Senate Floor

For the third time since 2008, the Senate Judiciary Committee has reported patent reform legislation (S. 23) out of committee for consideration by the full Senate. Some of the senators who agreed to approve the bill have reportedly indicated that they will not support it without amendments that they plan to bring to the floor. Business method patents are likely to be one of the issues that will come up for debate.

Among other matters, the proposal would adopt a first-to-file rule that a coalition of inventors calls "a race to the patent office [that would] put small inventors at a disadvantage." Under current law, exclusive patent rights are given to the inventor who first had the idea. The proposal would also drop a requirement that judges sitting on the Federal Circuit Court of Appeals bench live within 50 miles of the District of Columbia. The bill contains significant changes to the procedures governing post-grant review of issued patents, including a change to the threshold for granting review from a "substantial question of patentability" to a "reasonable likelihood of invalidity."

The bill apparently has the support of the American Intellectual Property Owners Association, Biotechnology Industry Organization and Pharmaceutical Research and Manufacturers of America. While it has bipartisan support, the Patent Reform Act of 2011 may languish as its predecessors have. No companion bill has yet been introduced the House. *See philly.com*, January 30, 2011; *The National Law Journal*, February 4, 2011.

NEW BIO BUSINESS VENTURES

Biomedicine Startup Launches in Cambridge, Massachusetts

Japanese pharmaceutical company Eisai has reportedly invested up to $200 million for research and development in a Cambridge, Massachusetts-based biotech startup devoted to developing the next generation of cancer treatments. Called H3 Biomedicine, the startup "will benefit from access to many of Eisai's

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SHB offers expert, efficient and innovative representation to life sciences clients facing complex biotech litigation and intellectual property and regulatory protocols. We know that the successful resolution of biotech-related matters requires a comprehensive strategy developed in partnership with our clients.

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drug development capabilities, allowing H3 Biomedicine to focus on first-in class drug discovery innovation," according to a joint press release.

Under the leadership of scientific founders Stuart Schreiber and Todd Golub, both of whom have reportedly transformed medical research, H3 Biomedicine will approach oncology treatment research on the basis of two fundamental principles: "the genetics of patients' cancers can reveal drug targets tailored to their cancers," and "the advances in modern chemistry enable the discovery of new classes of safe and effective drugs against these targets." According to the companies, the Eisai affiliation "will enable H3 Biomedicine to take a longer-term view of its drug discovery activities than is typical of many venture-backed start-up companies." *See Eisai/H3 Biomedicine Press Release*, January 27, 2011.

INVESTOR NEWS

Venture Investing Decreased in California in 2010, but Executives Bullish About Biotech Future

With biotechnology employing some 268,000 people in California, industry executives reportedly remain optimistic about its future in the state despite a recent report indicating that biotech venture investments decreased in 2010. More executives than ever indicate that they will be increasing their manufacturing in California, and about two-thirds plan to increase the size of their workforces in the state. Among the state's attractions to biotech entrepreneurs are skilled workers and access to top universities. According to the report, biopharmaceuticals apparently saw a 6.7 percent increase in global demand in 2010 with sales reaching $752 billion, and seven of the top 10 global biologic products were produced by California companies. *See Xconomy* (San Francisco), February 1, 2011.

BUSINESS CLIMATE

Tax Reforms on Administration's Agenda

President Barack Obama's (D) State of the Union message included a call to overhaul the nation's tax code. With established companies often paying more than 30 percent of their income in taxes, others, such as those in the biotech industry, paid less than 5 percent in 2009. Taxation has long been used to advance public policy by supporting certain business sectors and industries over others, making the system unwieldy, complex and, in some respects, unfair. Still, some of those who would like to see loopholes closed would prefer lowering or eliminating all taxes for business, and not just equalizing the rates paid. According to most studies, the average corporate tax paid is 25 percent of income, even though the top corporate rate is 35 percent.

Corporate leaders have reportedly indicated to some members of Congress that they would prefer the imposition of a single lower tax rate for all while foregoing the application of various deductions that change from year to year. *See The New York Times*, January 27, 2011.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

U.S. Patent and Trademark Office Proposes First of "3-Track" Patent Processing Program

The U.S. Patent and Trademark Office (USPTO) has issued a **proposed rule** that will allow applicants speedier patent processing in exchange for a $4,000 fee. The proposal details "Track I" of a "3-Track" patent processing program, first published for public comment in June 2010, to enable applicants to choose the speed at which their applications are processed. After receiving much public support, Track I, also known as the Prioritized Examination Track, has been slated by USPTO for immediate implementation. USPTO requests comments by March 7, 2011.

Track I's proposals include (i) giving applicants "the opportunity for prioritized examination of a patent within 12 months of its filing date for a proposed fee of $4,000," (ii) limiting claims to four independent claims and 30 total claims, and (iii) filing through USPTO's electronic filing system. USPTO also plans to limit the number of applications to 10,000 in the program's first year and to complete "nearly all of the 313,000 oldest backlog applications" by the end of 2011. Only new applications will be eligible for the proposed fast-track program.

USPTO also plans to offer to "smaller entities" a 50-percent discount on Track I filing fees. "The patent reform legislation recently introduced in the U.S. Senate would enable the USPTO to set its own fees and thereby extend this discount to small entity applicants," according to the agency. "The Patent and Trademark Office plays a key role in promoting innovation and entrepreneurship," U.S. Commerce Secretary Gary Locke was quoted as saying. "This new system will bring the most valuable patents, as determined by inventors, to market faster and will help shrink the backlog by catering to the business needs of America's innovators." *See USPTO Press Release,* February 2, 2011; *Federal Register,* February 4, 2011.

Biotech Crops Gain Momentum

The U.S. Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service (APHIS) has decided to partially deregulate sugar beets that have been genetically modified (GM) to resist Monsanto Co.'s Roundup Ready® herbicide. Representing an interim measure until APHIS completes a full environmental impact statement by May 2012, the decision means that farmers can continue planting GM sugar beets under strict conditions despite a federal court ruling in August 2010 that governmental approval of the beets violated environmental law.

"After conducting an environmental assessment, accepting and reviewing public comments and conducting a plant pest risk assessment, APHIS has determined that the Roundup Ready sugar beet root crop, when grown under APHIS imposed conditions, can be partially deregulated without posing a plant pest risk or having a significant effect on the environment," said an APHIS spokesperson.

Under the partial deregulation, GM sugar beet farmers "will be required to enter into a compliance agreement that outlines mandatory requirements for how the crop can be grown," according to APHIS. The agency retains "the discretion to revoke, withdraw, or otherwise cancel the conditional partial deregulation for root crop production" and impose civil or criminal penalties and remedial measures to those in violation, such as seizure, quarantine or crop destruction. Notice of the decision will be published in the *Federal Register*. *See USDA News Release,* February 4, 2011.

In a related matter, the U.S. Fish and Wildlife Service has issued a **draft environmental assessment** concerning the potential effects of genetically modified glyphosate-tolerant (Roundup Ready®) corn and soybean crops on land in the National Wildlife Refuge System. Part of a habitat restoration program that affects Colorado, Kansas, Montana, Nebraska, North Dakota, Utah, and Wyoming, the crops provide "effective control and elimination of noxious weeds and other undesirable plants prior to the area being reseeded to native grasses and wildflowers," according to the agency. Comments are requested by March 4, 2011. *See U.S. Fish and Wildlife Service Press Release,* February 2, 2011.

LITIGATION

Court Dismisses Fraud Claims Against Investors Who Sued Biotech Startup

A federal court in California has granted in part the motion that two biotech startup investors filed under the state's anti-SLAPP (strategic lawsuit against public participation) law to dismiss the company's counterclaims against them. *Albergo v. Immunosyn Corp.*, No. 09-02653 (U.S. Dist. Ct., S.D. Cal., decided January 20, 2011). The investors alleged that they were defrauded into signing a second contract as part of their deal to provide $1.25 million to the company in exchange for 102,500 shares of stock that they purportedly never received. They sued the company for breach of contract, violations of the Securities Exchange Act, fraud, RICO violations, conspiracy, unjust enrichment, and fraudulent conveyance.

The company filed a counterclaim alleging breach of contract, fraud, and intentional and negligent inference with economic advantage. Essentially, the company alleged that by seeking to enforce the contracts through their complaint, the investors made false claims in their complaint and interfered with the company's attempt to sell shares by seeking relief through the court.

When the investors filed a special anti-SLAPP motion, contending that the company was attempting to punish them for exercising their constitutional rights, the defendant responded that the investors rescinded their first contract by signing the second contract and that they breached the agreements in the second contract to release and hold harmless the defendant for claims arising out of the first contract. The defendant also argued that it had made a *prima facie* showing that it would likely prevail on its counterclaims, an element needed to defeat an anti-SLAPP motion.

Explaining that the anti-SLAPP statute applies to protect an individual's right to file a lawsuit, the court determined that the defendant had not, in fact, shown that it was likely to prevail on its counterclaim as to breach of contract because it had not alleged the existence of each of the necessary elements for this claim. As to the company's fraud counterclaim, the court noted that the company's allegations were based on claims the investors made in the complaint, which "are privileged" under state law, which privilege "bars all tort causes of action, other than malicious prosecution." Thus, the court granted the investors' motion as to the fraud counterclaim. While the court found that the anti-SLAPP statute applied to the company's counterclaims for interference with economic advantage, it allowed the company to conduct limited discovery on the issue and deferred ruling on it.

NEWS BYTES

The U.S. Patent & Trademark Office **announces** an agreement with the European Patent Office on a joint patent classification system that "will use the European Classification System as a basis and incorporate the best classifications practices of the USPTO." The system will also be more detailed than the International Patent Classification system "to improve patent searching."

The journal *Cell Stem Cell* releases **results** from a November 2010 survey of 370 scientists showing that uncertainty over the legal challenge to the Obama administration's human embryonic stem cell research policy has had negative scientific and economic ramifications.

The Kansas Bioscience Authority (KBA) **schedules** a February 15, 2011, Webinar to provide information about a U.S. Department of Agriculture Agricultural Research Service program designed "to aggressively increase commercialization of federal research innovations for maximum economic impact." KBA is a strategic partner in the "Agricultural Technology Innovation Partnership" and will work "with researchers, businesses, and organizations to spin federal research out of labs and accelerate economic growth in this region."

UPCOMING CONFERENCES AND SEMINARS

Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Partner **Michelle Fujimoto** will join a distinguished panel of speakers addressing

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biotech industry developments at the Midyear Meeting of the International Association of Defense Counsel (IADC). Scheduled for February 19-24, 2011, in Pebble Beach, California, this conference features a number of presentations, including the Drug, Device and Biotechnology Committee's program, "The Immediate Future: What Practitioners Need to Know Regarding Developments in the Industry and Their Impact on the Practice of Law." Fujimoto will join three other speakers during this program to discuss issues likely to affect the industry over the next five years, including "the increased use of nanotechnology, biopharmaceuticals, and biosimilars," how these developments may affect the business side of the industry and their likely effects on litigation practices.

Shook, Hardy & Bacon Intellectual Property & Technology Litigation Associate Jason Mudd will join several panels of distinguished scholars February 25, 2011, for a Missouri Law Review symposium on "Evolving the Court of Appeals for the Federal Circuit and Its Patent Law Jurisprudence." The keynote speaker for the event, which will be held at the University of Missouri School of Law in Columbia, Missouri, is U.S. Patent and Trademark Office Director David Kappos. Mudd's panel presentation will focus on "The Court's Impact on Innovation, Industry and the Practice of Law."

Shook, Hardy & Bacon Intellectual Property Partner Peter Strand will lead a session on communicating with jurors at DRI's Business Litigation and Intellectual Property Seminar slated for April 14-15, 2011, in Chicago, Illinois. Titled "A Thousand Words More or Less: Effectively Using Visuals at Trial," the presentation will address "the 'whys' and 'hows' of teaching and persuading jurors using the entire panoply of visual media." ■

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Shook, Hardy & Bacon attorneys are experienced at assisting biotech and life sciences clients with a variety of legal matters such as U.S. and foreign patent procurement; licensing and technology transfer; venture capital and private financing arrangements; joint venture agreements; patent portfolio management; biomedical research and development; risk assessment and management; records and information management issues and regulations; and employment matters, including confidentiality and non-compete agreements. The firm also counsels industry participants on compliance issues, ranging from recalls and antitrust matters to facility inspections, subject to FDA, SEC, FTC, and USDA regulation.

SHB is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most challenging national and international product liability and mass tort litigations.